IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALKEM LABORATORIES LTD., *Plaintiff*, v. AVADEL CNS PHARMACEUTICALS, LLC, *Defendant*.	:	C.A. No. _____

COMPLAINT

Plaintiff Alkem Laboratories Ltd. ("Plaintiff" or "Alkem") brings this action against Defendant, Avadel CNS Pharmaceuticals, LLC ("Defendant" or "Avadel") for refusal to provide access to pharmaceutical product samples under the Creating and Restoring Equal Access to Equivalent Samples Act (Section 610 of Division N of the Further Consolidated Appropriations Act, 2020, codified at 21 U.S.C. § 355-2 ("CREATES Act" or "Act")).

NATURE OF THE ACTION

1. Defendant sells LUMRYZ® (sodium oxybate 4.5gm/packet, 6 gm/packet, 7.5 gm/packet, 9 gm/packet for extended-release oral suspension), an oral medication used to treat cataplexy or excessive daytime sleepiness in patients with narcolepsy, and cataplexy. Avadel obtained marketing approval for LUMRYZ® from the U.S. Food and Drug Administration ("FDA") on May 1, 2023, pursuant to an earlier-filed New Drug Application No. N214755.

2. LUMRYZ® is Avadel's only FDA-approved revenue-generating product. On information and belief, for the fiscal year ending June 30, 2024, Avadel's net revenue from LUMRYZ® totaled $96 million.

3. Alkem seeks to develop a generic version of LUMRYZ®. Alkem, an experienced generic product developer, is a leading generic drug manufacturer with a legacy of 50 years in providing high-quality medicines to patients throughout the world. Alkem and its affiliates have 19 state-of-the-art manufacturing facilities and cutting-edge research and development centers at multiple locations in India and the United States to develop and manufacture generic formulations, active pharmaceutical ingredients and biosimilars.

4. To obtain marketing approval for a generic version of LUMRYZ®, Alkem must submit an Abbreviated New Drug Application ("ANDA") to the FDA. The FDA requires such an ANDA to include analytical and bioequivalence testing data comparing LUMRYZ® to Alkem's proposed generic product. To perform the required testing, Alkem needs to obtain LUMRYZ® product samples from Avadel.

5. Congress has recognized that NDA holders may have a financial incentive to delay providing, or outright refuse to provide, generic product developers with sufficient drug samples to support an ANDA filing. Accordingly, Congress passed the CREATES Act, which states the purpose of which is "[t]o promote competition in the market for drugs and biological products by facilitating the timely entry of lower-cost generic and biosimilar versions of those drugs and biological products."

6. The CREATES Act provides a timeline and mechanism for a generic product developer (like Plaintiff, here) to obtain sufficient quantities of a covered drug product from the holder of an approved NDA, on commercially reasonable, market-based terms. Under Section (b)(2)(iv)(I) of the Act, the license holder must provide those quantities within 31 days after receiving the request from the generic product developer/Section (a)(10) of the Act further specifies that "sufficient quantities" means "an amount of a covered product that the ***eligible***

product developer determines allows it" to conduct testing to support an ANDA, and to fulfill any regulatory requirements relating to approval.

7. Congress added the language bolded above to the final, as-passed version of the CREATES Act after the FDA recommended it do so in March 2019. In comments supporting this proposed amendment, the FDA expressed concern that "[a]s currently written, the bill leaves room for disagreements between the license holder and the eligible product developer as to the quantity of covered product needed by the eligible product developer to develop their product and submit an application. [] Because a license holder's failure to provide sufficient quantities can stymie an eligible product developer's development program and prevent the submission of an application to FDA, this lack of specificity could result in license holders and eligible product developers needing to litigate cases that would otherwise not require litigation, which could slow (or entirely prevent) drug development." The FDA further commented that "[w]e believe these edits will help eliminate opportunities for gamesmanship in this area that could delay or prevent drug development." See **Exhibit A**, attached, at 2-3.

PARTIES

8. Alkem Laboratories Ltd. is a corporation organized and existing under the laws of the Republic of India with a place of business at Alkem House, Senapati Bapat Marg, Lower Parel, Mumbai, Maharashtra, India 400 013.

9. On information and belief, Defendant, Avadel CNS Pharmaceuticals, LLC, is a corporation organized and existing under the laws of the State of Delaware, with a Principal Office located at 3411 Silverside Road, Tatnall Building, Suite 104, Wilmington, Delaware 19810.

10. On information and belief, Defendant, Avadel CNS Pharmaceuticals, LLC, has a registered agent, Corporate Creations Network Inc., with a registered address located at 1521 Concord Pike, Suite 201, Wilmington, Delaware 19803.

JURISDICTION AND VENUE

11. Alkem's claim for failure to provide access to pharmaceutical product samples arises under the CREATES Act, 21 U.S.C. § 355-2. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §1331 and 21 U.S.C. §355-2(b)(1).

12. This Court has personal jurisdiction over Avadel because Avadel maintains a principal place of business in this district, conducts continuous and systematic business activities in this district, and has committed acts in this district giving rise to Alkem's claims.

13. Venue is proper in the District of Delaware under 28 U.S.C. § 1391 because Avadel's principal place of business is in this judicial district, where a substantial part of the events giving rise to this claim occurred.

BACKGROUND

14. Alkem applied for, and received, approval of its request for Covered Product Authorization (CPA) for LUMRYZ® (sodium oxybate) extended-release oral suspension, 4.5 gm/packet, 6 gm/packet, 7.5 gm/packet, 9 gm/packet from FDA on March 21, 2024 (the "FDA Letter Granting CPA".) *See* **Exhibit B**.

15. FDA determined that Alkem's protocols included safety protections comparable to those provided by the REMS for Lumryz, such that FDA authorized Alkem to obtain sufficient quantities of Lumryz to conduct testing in support of its ANDA. And further defines suficient quantities as "…an amount of Lumryz that Alkem determines allows it to conduct testing to

support an abbreviated new drug application (ANDA) and fulfill any regulatory requirements relating to approval of such an ANDA. 21 U.S.C. 355-2(a)(10). Ex. B at ¶1.

16. Pursuant to Section (b)(2) of the CREATES Act, Alkem Laboratories Ltd. submitted an initial request to Avadel seeking to purchase 19 packs of 4.5 mg strength of LUMRYZ®. This initial request was dated April 23, 2024 and transmitted on May 31, 2024 (the "Initial Request".) *See* **Exhibit C**.

17. Accordingly, on May 31, 2024, Alkem submitted a written request to Avadel to purchase sufficient quantities of LUMRYZ®. This request was sent to Avadel CNS Pharmaceuticals, LLC, to the attention of Jerad Seurer, LLC; specified Rise Pharma LLC as the primary point of contact for Avadel to direct communications related to the sale of LUMRYZ® to Alkem, including email, telephone and office addresses; and specified an address to which the LUMRYZ® was to be shipped upon reaching an agreement to transfer it. *See* Ex. C. This request was delivered to Avadel via USPS Certified Mail, Return Receipt Requested on May 31, 2024. See Ex. C, attached.

18. The Initial Request was valid and proper under the CREATES Act.

19. On May 6, 2024, Avadel CNS Pharmaceuticals, LLC issued a letter responding to Alkem's Initial Request directed to Rise Pharma LLC, Alkem Laboratories Ltd.'s authorized purchasing agent (the "First Response Letter".) *See* **Exhibit D**. The First Response Letter was dated May 6, 2024, but was not received by Alkem or its designated representative until July 23, 2024.

20. Avadel's First Response Letter stated that, "…Avadel currently lacks inventory of LUMRYZ to supply Rise Pharma LLC with development samples while still ensuring sufficient

supply to meet the needs of the growing patient population for LUMRYZ." First Response Letter at ¶3.

21. On July 30, 2024, Counsel for Alkem, Kratz & Barry LLP, issued a demand letter to Avadel citing, among other things, Avadel's First Response Letter refusing Alkem's request for samples as deficient in violation of the CREATES Act (the "K&B Demand Letter"). *See* **Exhibit E** at ¶ 2.

22. Avadel delivered a response to the K&B Demand Letter dated August 5, 2024 (the "Avadel Response to K&B Demand Letter"). *See* **Exhibit F**.

23. Avadel's Response to K&B Demand Letter again did not dispute that Alkem made a proper CREATES Act request, but continued to feign its ability to be able to provide samples based on the "inventory available at the time of the request" (*see* Ex. F at ¶3) and continued to assign blame on the U.S. Drug Enforcement Administration (DEA), stating, "…Avadel's procurement of the Schedule I controlled substance gamma hydroxybutyrate ("GHB") and Avadel's manufacture of LUMRYZ with its GHB-derived active ingredient are both limited by annual quotas established by the DEA." (*see* Ex. F at ¶2.)

24. As of the date of this filing, Avadel still has not provided the 19 packs of 4.5 mg strength of LUMRYZ® sought in the Initial Request.

25. Avadel's refusal to provide the requested quantity of LUMRYZ®, which Alkem had determined was necessary to allow Alkem to conduct testing to support approval of its planned ANDA, violates the CREATES Act.

26. Avadel has failed to provide sufficient quantities of LUMRYZ® to Alkem, and in fact has refused to do so, apparently in an effort to delay potential generic competition to LUMRYZ®.

COUNT I

Failure to Provide a Covered Drug Product in Violation of 21 U.S.C. § 355-2(b)

27. Alkem incorporates each of the preceding paragraphs 1-25 as if fully set forth herein.

28. As of the date of the filing of this action, Alkem has not obtained sufficient quantities of LUMRYZ® on commercially reasonable, market-based terms.

29. As of close of business on July 1, 2024, the deadline under the CREATES Act, Avadel had neither delivered to Alkem sufficient quantities of LUMRYZ® on commercially reasonable, market-based terms nor has Avadel delivered such quantities to Alkem at any time to date, as of the date of filing of this Complaint.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, Alkem Laboratories Ltd. prays for judgment against Defendant, Avadel CNS Pharmaceuticals, LLC, Inc. and requests the following relief:

A. A judgment that Avadel has failed to provide sufficient quantities of LUMRYZ® to Alkem, in violation of 21 U.S.C. § 355-2;

B. An immediate order under 21 U.S.C. § 355-2(b)(4)(A)(i) and (b)(4)(C) directing Avadel CNS Pharmaceuticals, LLC to provide Alkem Laboratories Ltd., without delay, sufficient quantities of LUMRYZ® on commercially reasonable, market-based terms, including the quantity sought by Alkem in its April 23, 2024 Initial Request under the CREATES Act;

C. An award to Alkem of its reasonable attorney's fees and costs for this action;

D. An award to Alkem of a monetary amount sufficient to deter Avadel from failing to provide eligible product developers with sufficient quantities of a covered product on commercially reasonable, market-based terms, under 21 U.S.C. § 355-2(b)(4)(A)(iii); and

E. An award of all such other relief as this Court deems just and proper.

Dated: August 13, 2024

KRATZ & BARRY LLP

/s/ R Touhey Myer

R Touhey Myer (#5939)
800 N. West Street
Wilmington, DE 19801
(302) 527-9378
tmyer@kratzandbarry.com

Of Counsel:

Timothy H. Kratz *(Pro Hac Vice Anticipated)*
George J. Barry III *(Pro Hac Vice Anticipated)*
John Thallemer *(Pro Hac Vice Anticipated)*
KRATZ & BARRY LLP
1050 Crown Pointe Parkway, Suite 500
Atlanta, GA 30338
(404) 431-6600
tkratz@kratzandbarry.com
gbarry@kratzandbarry.com
jthallemer@kratzandbarry.com

Michael P. Hogan *(Pro Hac Vice Anticipated)*
KRATZ & BARRY LLP
325 Chestnut Street, Suite 883, #259
Philadelphia, PA 19106
(917) 216-8585
mhogan@kratzandbarry.com

Attorneys for Plaintiff,
Alkem Laboratories Ltd.